

### REMARKS

Claims 21-40 are pending in this application. Claims 26 and 36 have been amended to place claim 26 in independent form and amend claim 36 to simply overcome an objection raised by the Examiner. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

#### Interview with Examiner Tyson and Supervisory Examiner Nguyen

At the Request of Applicants, an Examiners Interview took place on October 6, 2006 between Applicants Representative James McPherson and Examiner Tyson and Supervisory Examiner Nguyen. The purpose of this Interview was to discuss the pending claims of the application and the validity of the rejections to Independent claims 21, 32 and 37. Applicants would like to thank both of the Examiners for the courtesy and time extended to Applicants representative during this Interview.

During this Interview, an agreement was not reached between Applicant's Representative and the Examiners. Below is a summary of the claims, issues presented by Applicants Representative and the Examiner's Responses thereto. In view of the comments made herein Applicants request reconsideration.

#### Independent claim 21

Applicant's Representative point out that claim 21 currently stands rejected under §102 based upon U.S. Patent No. 5,853,366, to Dowlatshahi and particularly points out that "wherein the clip unfolds upon itself about the first apex by rotating greater than 90° relative to an opposing portion" is not expressly or inherently taught by Dowlatshahi because it is not a necessary feature of the Dowlatshahi clip. Applicant's Representative state that at most, the Dowlatshahi clip, by design, is only capable of unfolding to 90° upon deployment because, at most, the legs of the clips are mounted at maximum of 90° with respect to one another and the specification, through the drawings, only teaches compression of approximately 40° with respect to one another. Accordingly, even if the clip was to be compressed to 0° it could only unfold to a maximum of 90°. However, if this was done, it is possible or even likely that plastic deformation of the clip would result preventing the clip from completely

unfolding. There is no support, in Dowlatshahi, that this much compression of the "V" shaped clip, as shown in the drawings and described within the written description, is desired or even possible.

The Examiner asserts that this limitation is a process or method limitation and since the claim is an apparatus claims the disputed claim limitation of the clip cannot be considered because there is no structural support for this ability. The Examiner then asserts that if the limitation was in a method claim it could be considered.

Applicant's Representative respectfully disagrees.

#### Independent claim 37

Applicant's Representative next references claim 37 and point out that this claim is a method claim and includes the same unfold feature of claim 21 and therefore the Examiner must now consider this feature. The Examiner agrees that the specific range of motion of the Dowlatshahi clip is not specifically taught in the specification. However, the Examiner takes the position that the drawings show that the legs of the clip are farther apart than 90° and that the end of the clip could be pressed together and released to allow for unfolding greater than 90°.

In response, Applicant's Representative argue that patent law teaches that the drawings should not interpreted for exact dimension and that the specification is clear that, at most, the legs of the clips are attached at 90° with a preferred range much less. Applicant's Representative further point out that there is no teachings in the reference that bending of the clip in such a manner is desired or even possible in view of the potential plastic deformation of the clip during compression.

The Examiner maintains his position that he believes that the clip is capable of this motion and further states that 90° is too close to the prior art. Applicant's Representative then point to the claim language recited in claim 26 which recites that the clip unfolds 180° and state that this is clearly beyond the teachings of the prior art.

After contemplation, the Examiner takes the position that clip in the prior art, which teaches unfolding of approximately 45° or less, is capable of unfolding upon itself by 180°.

Applicant's Representative argue that there is absolutely no teaching, desirability or even capability of the clip of the prior art being capable of this.

Examiner asserts that he believes that the legs of the Dowlatshahi clip, despite the lack of teachings within the reference, can be elastically rotated to 180° and would return to its position without plastic deformation.

Applicant's Representative respectfully disagrees.

#### Independent claim 32

Applicant's Representative point out the last independent claims and assert that "a gripping portion having two opposing semicircular or substantially circular finger grips attached to a hub portion" is clearly not taught by the prior art.

The Examiner asserts that the claim is not clear whether there includes: i) two opposing semicircular or two substantially circular finger grips or ii) two opposing semicircular and one substantially circular finger grip. Accordingly, in its broadest scope, the prior art teaches a circular finger grip and anticipates the claims.

Applicant's Representative respectfully disagrees.

#### Claim Objections

Claim 36 is currently objected to for being dependent upon a clip and not the device. Pursuant to the Examiner's suggestion, Applicants have amended claim 36 to be dependent upon the device of claim 32 as opposed to the clip of claim 30. Applicants believe this amendment rendered this objection moot.

#### Claim Rejections under 35 U.S.C. §102

Claims 21-22 and 25-29 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,853,366, to Dowlatshahi. Applicants respectfully disagree. The Examiner's arguments within the Office Action and Interview assert that the missing features of the claims, not taught by Dowlatshahi, would be inherent because it is possible to bend the clip of Dowlatshahi in a manner described in the claims. Not only is this unsupported by the teachings of Dowlatshahi; but, it is also in contrast with legal precedence with regards to the use of inherency.

#### Applicable Law for Anticipation with Inherency

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "A patent applicant is free to recite features of an apparatus either structurally or functionally." In re Schreiber, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997), also See In re Swinehart, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. See Manual of Patent Examining Procedures (MPEP) § 2173.05(g). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. The court in In re Swinehart, stated:

where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

In re Swinehart, 439 F.2d at 213, 169 USPQ at 228, also see also In re Hallman, 655 F.2d 212, 215, 210 USPQ 609, 611 (CCPA 1981); In re Ludtke, 441 F.2d 660, 663-64, 169 USPQ 563, 565-67 (CCPA 1971). Also, a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all of the structural limitations of the claim, expressly or through inherency. See MPEP §2114.

#### Examiner's Burden of Providing Rationale or Evidence Tending to Show Inherency

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004).

#### Application of Law

In the present application, claim 21 recites "wherein the first and second portions are adapted to permit the clip to compress to fit within a tube of a delivery device and to elastically deform upon exiting the tube for engaging tissue... the clip unfolds upon itself about the first apex by rotating greater than 90° relative to an opposing portion." Pursuant to legal precedent, the Examiner is required to consider this claim feature and this feature is not expressly or inherently taught by Dowlatshahi.

In the Final Office Action, Examiner Tyson assert that clip is deformable and resilient and that "the clip...of Dowlatshahi is inherently capable of unfolding upon itself about the first apex...by rotating greater than 90 degrees relative to an opposing portion, if the orientation of the clip...in the guide tube is changed such that it would have to rotate greater than 90 degrees in order to resume its original size and shape.

In the Interview, Supervisory Examiner Nguyen Acknowledges that the Dowlatshahi clip does not expressly teach the clip unfolding upon itself by rotating greater than 90° as described in claims 21 and 37; however, the Examiner asserts that he believes that the clip can be bent to a certain degree and released to teach the claim limitations. Also, the Examiner asserts that since it is a functional limitation that it cannot be used to distinguish the clip over the prior art, without structural support.

Applicants are of the opinion that in both the Final Office Action and Examiner Interview, the Examiner(s) have failed to properly present a case of anticipation as all of the claim features are not expressly or inherently taught. Even if the disputed claim passage of rotation is considered to be functional language and not a physical structural feature, the functional language still must be considered for patentability of the claim.<sup>1</sup>

Applicants note that both in the Final Office Action and during the Interview, the Examiners do not assert that the specific rotating claim feature is taught by Dowlatshahi expressly, but instead inherently. As previously mentioned, with the use of Inherency for formulating a rejection, the Examiner "must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flow from the teachings of the applied prior art."<sup>2</sup> Also, the Examiner is barred from establishing this by "probabilities or possibilities."<sup>3</sup> Still further, the Examiner is barred from asserting the "a certain thing may result from a given set of circumstances."<sup>4</sup>

In view of the foregoing, the Examiners asserted rejection of claim 21 is improper because the Examiners have failed to assert, or even hint, why the clip of Dowlatshahi "**necessarily**" must be capable of unfolding upon itself about the first apex by rotating greater than 90° relative to an opposing portion, let alone 180° as recited in claim 26. Nothing in the teaching of Dowlatshahi teaches or suggests that this feature is necessary in order for Dowlatshahi to function as envisioned. Furthermore, the drawings of the "V" shaped clip and limited rotational movement described in Dowlatshahi teaches that this rotational unfolding is not even contemplated. In contrast, Dowlatshahi teaches very specific and limited movement.

Second, the Examiners improperly used "**probabilities or possibilities**" in formulating the rejections by asserting rationalization that the Dowlatshahi clip is capable of such claim features: "if the orientation of the clip...in the guide tube...is changed such that it would have to rotate greater than 90 degrees in order to resume its original shape."<sup>5</sup> Furthermore, in the Interview, the Examiner assertions that if the

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<sup>1</sup> See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) and MPEP §2114

<sup>2</sup> *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

<sup>3</sup> *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

<sup>4</sup> *In re Rijkkaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

<sup>5</sup> See Final Office Action, p. 3.

clip was bent, in a manner other than what is taught by Dowlatshahi, that it would be possible for the Dowlatshahi clip to unfold in such a manner. Both of these assertions are improper because not only are these probabilities or possibilities of what the Dowlatshahi clip may be able to do, but such possibilities are clearly well beyond the disclosure of Dowlatshahi.

Third, the Examiners use of possible alterations to the teachings of Dowlatshahi assert **“a certain thing may result from a given set of circumstances”**, which is also in violation of legal precedence. Specifically, the Examiners are presenting the circumstance of what may happen to the Dowlatshahi clip if it is bent or rotated to a position, outside the maximum range taught by Dowlatshahi, but within the range of the claims as recited.

At a minimum, for the above reasons the rejections to claim 21-22 and 25-29 are believed to be traversed. Accordingly, claim 21 is in condition for allowance. Likewise, claim 26, which has been rewritten to include all of the features of the claim 21 and includes rotation greater than 180° is also believed to be allowable. Further, dependent claims 22-25 and 27-31 are believed to be allowable for being dependent upon claim 21.

Claim 32 currently stands rejected under 35 U.S.C. §102(b) as being anticipated by PCT Publication No. WO 00/24320, to Esposito et al. Applicants respectfully disagree.

The Examiner's asserts in the Final Office Action, and during the Interview, that the claims feature “a gripping portion having two opposing semicircular or substantially circular finger grips attached to a hub portion” can be interpreted as i) two opposing semicircular or two substantially circular finger grips or ii) two opposing semicircular and one substantially circular finger grip. The Examiner asserts that Esposito et al., Figure 3, shows one substantially circular finger grip. Applicants are of the opinion that the Examiner has misinterpreted the clear meaning of the claim.

Applicants note that the claim clearly recites “grips” as oppose to “grip”. This requires, and is clearly supported by the written description and drawings, that the gripping portion must include more than one finger grip meaning that there are two finger grips (e.g. two opposing semicircular finger grips or two substantially circular finger grips).

In view of this clarification, Applicants believe the rejection to claim 32 has been traversed and that claim 32 is in condition for allowance.

Claim Rejections under 35 U.S.C. §103

Claims 23, 24, 27, 28, 30, 31 and 37- 40 currently stand rejected under 35 U.S.C. §103 as being obvious in view of U.S. Patent No. 5,853,366, to Dowlatshahi, and in some instances in further view of U.S. Patent No. 6,371,904, to Sirimanne et al., U.S. Patent No. 6,234,177, to Barsch, and/or U.S. Patent No. 6,549,800, to Atalar et al. Applicants respectfully disagree.

Each of the formulated rejections relies upon the teachings Dowlatshahi to teach the claim feature "wherein the clip unfolds upon itself about the first apex by rotating greater than 90° relative to an opposing portion". In view of the foregoing discussion with regards to claims 21, the rejections to independent claims 21 and 37 are believed to be traversed and the claims in condition for allowance. Accordingly, claims 23, 24, 27, 28, 30, 31 and 37- 40 are believed to be in condition for allowance.

Claims 33-36 currently stand rejected under 35 U.S.C. §103 as being obvious in view of PCT Publication No. WO 00/24320, to Esposito et al., and in some instances in further view of PCT Publication No. WO 00/67833, to Klein et al., U.S. Patent No. 6,220,248, to Voegele et al. and/or U.S. Patent No. 5,853,366, to Dowlatshahi.

In view of the previous discussion with regards to independent claim 32, it is believed that independent claim 32 is in condition for allowance. Since claims 33-36 are dependent upon claim 32, it is believed that these claims are also in condition for allowance. Accordingly, this rejection to claims 33-36 under 35 U.S.C. §103 are traversed.

By amending the application, the Applicants do not concede that the patent coverage available to them would not extend as far as the original claim. Rather, Applicants reserve the right to file a continuation application to pursue the breadth of the claims as filed. Applicants believe that the Examiner has not made a sufficient showing of inherency of the teachings of the asserted prior art, especially given the



lack of teachings in the cited references of the properties that Applicants have recited in their claims.


Further, by the present amendment, it does not follow that the amended claims have become so perfect in their description that no one could devise an equivalent. After amendment, as before, limitations in the ability to describe the present invention in language in the patent claims naturally prevent the Applicants from capturing every nuance of the invention or describing with complete precision the range of its novelty or every possible equivalent. See, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 62 USPQ2d 1705 (2002). Accordingly, the foregoing amendments are made specifically in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicants would otherwise be entitled.

### CONCLUSIONS

In view of Applicants' amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicants submit that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-1097 for any fee which may be due.

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